



**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

Public Health Service

d1893b

**Food and Drug Administration**  
555 Winderley Place, Suite 200  
Maitland, Florida 32751

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

**WARNING LETTER**

FLA-98-55

June 24, 1998

Mr. Tedd T. Vurraro  
Owner and President  
Nature's Choice Aloe Products  
1251 E. Sample Road  
Pompano Beach, Florida 33064

Dear Mr. Vurraro:

During an inspection of your firm on January 22, 23, and 27, 1998, FDA Investigator Michelle S. Dunaway found that your firm distributed Nature's Choice Aloe Vera Juice which is labeled and promoted for conditions which cause it to be considered a drug.

Nature's Choice Aloe Vera Juice is considered a drug because of claims, such as the following, declared on its labeling:

- relief from Ulcers, Arthritis, Diabetes
- cure for hangover, hemorrhoids, vaginitis, insomnia

Because these claims suggest that the product is intended for use in the cure, treatment, or prevention of disease conditions, the product is a drug within the meaning of section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act).

The product is also a "new drug" [section 201(p) of the Act] because it is not generally recognized as safe and effective for the claimed conditions and it has not been approved for these purposes (section 505 of the Act).

The drug, Nature's Choice Aloe Vera Juice, is misbranded within the meaning of section 502(a) in that its labeling is false and misleading because it suggests that the drug is safe and effective for its intended use when this has not been established and because the labeling fails to bear adequate directions for use [section 502(f)(1) of the Act].

Mr. Tedd T. Vurraro  
Page 2  
June 24, 1998

This letter is not intended to be an all inclusive review of all labeling and products your firm markets. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

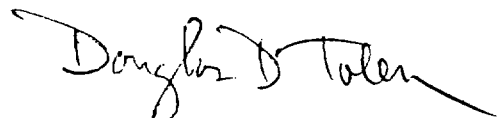
We are also aware of additional unsubstantiated claims appearing in brochures you prepared and make available upon request and claims you present on your web pages. These claims establish that Nature's Choice Aloe Vera Juice is intended to be used as a drug. Testimonial statements you placed on the web page include the claim that Nature's Choice Aloe Vera Juice has increased T4 cell counts in an HIV positive patient. This claim demonstrates the intended use of your product as a drug treatment for HIV/AIDS.

We request that you take prompt action to correct these violations. Failure to promptly correct violations may result in enforcement actions being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug, and Cosmetic Act provides for seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

Please notify this office in writing within 15 working days of receipt of this letter as to the specific steps you have taken to correct the stated violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be implemented.

Your reply should be sent to the Food and Drug Administration, Florida District, 555 Winderley Place, Ste. 200, Maitland, Florida 32751, Attn: Martin E. Katz, Compliance Officer, telephone no. (407) 475-5729.

Sincerely,

A handwritten signature in dark ink, appearing to read "Douglas D. Tolen", with a stylized flourish extending from the end.

Douglas D. Tolen  
Director, Florida District